DEPARTMENT OF HEALTH & HUMAN SERVICES

MAY 6 2008

Food and Drug Administration
Rockville MD 20857

Re: Macroplastique Implants

The Honorable Jon Dudas
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Dudas:

This is in regard to the applications for patent term extension for the following:

U.S. Patent Nos.	Docket No.
5,258,028	FDA-2008-E-0091
5,336,263	FDA-2008-E-0099
5,571,182	FDA-2008-E-0204

The applications were filed by Uroplasty, Inc., under 35 U.S.C. section 156. The medical device claimed by the patents is Macroplastique Implants, which was assigned premarket approval application (PMA) No. P040050.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. section 156(a)(4). Our records also indicate that it represents the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. section 156(f)(1).

The PMA was approved on October 30, 2006, which makes the submission of the patent term extension applications on December 20, 2006, timely within the meaning of 35 U.S.C. section 156(d)(1).

Should you conclude that the subject patents are eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. section 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the *Federal Register*, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Amy J. Hoffman
KAGAN BINDER, PLLC
221 Main Street North, Suite 200
Stillwater, MN 55082